

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2005239	(X3) Date Survey Completed 03/23/2021
Name of Provider or Supplier Partners Medical Clinic	Street Address, City, State 431 South 5th Street, Gadsden, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the AAB (American Association of Bioanalysts) proficiency testing (PT) records and an interview with Testing Personnel #1, the Office Manager, and the Laboratory Director, the surveyor determined the laboratory failed to submit results for the 2020-Event Q1 Nonchemistry survey before the cutoff date. This was noted on one out of seven 2018-2020 AAB survey events reviewed. The findings include: 1. A review of the PT records revealed results for the 2020-Event Q1 Nonchemistry (Hematology) survey were due on or before 02/19/2020. A review of Hematology records revealed the instrument was down and patient testing was suspended from 02/06/2020 to 02/29/2020. However, the laboratory failed to notify the PT program (AAB) of the problem within the time frame for submitting PT results; the laboratory scored 0%, with the code "NR" (Not reported to AAB) for this survey. 2. During an interview conducted on 03/23/2021 at 3:15 PM, Testing Personnel #1, the Office Manager, and the Laboratory Director confirmed the above noted findings, stating however that AAB proficiency program was notified before the survey was due; the surveyors requested documentation of the notification to AAB. 3. On 3/26/2021 the laboratory submitted additional documentation to CLIA via e-mail.</p>

The AAB records showed the laboratory failed to submit a valid reason for not performing the survey before the cutoff date. In a 3/29/2021 email, the Laboratory Director stated the Testing Personnel entered a comment, but probably forgot to save it. .

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on a review of 2018-2020 AAB (American Association of Bioanalysts) proficiency testing (PT) records and an interview with Testing Personnel (TP) #1 and the Laboratory Director, the laboratory failed to implement and document corrective actions for proficiency testing results less than one-hundred percent (%). This affected two out of seven PT events reviewed. The findings include: 1. A review of the survey results revealed no documentation of investigation or corrective action for two surveys with results less than 100%, as follows: A) 2019 Q1 NonChemistry (Hematology): Platelet Count with a score of 80%. B) 2020 Q1 NonChemistry (Hematology): Failure to submit PT results to AAB within the established timeframe which resulted in a score of 0% [Refer to D2123]; the laboratory further failed to perform an internal self-evaluation of their results to determine if corrective actions were needed. 2. In an interview on 3:15 PM on 03/23/2021, the surveyor reviewed the above findings were with Testing Personnel #1, the Office Manager, and the Laboratory Director. The surveyor asked if the Laboratory Director reviewed and performed corrective actions for AAB PT scores less than 100%; TP #1 stated they did not know this was required for the Platelet Count with a score of 80%, and did not know the laboratory was required to perform a self-evaluation comparing the laboratory's results with the peer group's results for 2020 Q1 NonChemistry. .

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the Medonic Hematology analyzer calibration records, the Medonic User's Manual and an interview with Testing Personnel (TP) #1 and Laboratory Director, the laboratory failed to perform a calibration at least every six months as per manufacturer's instructions. The laboratory failed to perform one of two calibrations due in 2019. The findings include: 1. A review of the Medonic Hematology records revealed a calibration was performed on 06/19/2019 by TP #1.

The next calibration was not performed until 03/05/2020, nine months after the previous calibration date. 2. A review of the Medonic User's Manual on page 59, "Section 7: Calibration", revealed "Introduction ... It is recommended to calibrate the instrument every six months. ..." 3. The surveyor requested the missing calibration record during the survey, however TP#1 was unable to provide the documentation. 4. In an interview on 03/23/2021 at 3:08 PM, the surveyor asked how often the Medonic should be calibrated; TP #1 stated every six months.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a lack of Hematology documentation and an interview with Testing Personnel (TP) #1, the laboratory failed to implement and document a mechanism to monitor quality control (QC) shifts and trends over time since the previous survey on 5/31/2018. The findings include: 1. A review of the QC records for the Clinical Diagnostic Solutions Medonic M-Series Hematology analyzer revealed only the daily QC printouts were available for review. The laboratory had no mechanism to monitor QC shifts and trends over time. 2. A review of the Medonic User's Manual on pages 56-57, Section 6.2, revealed "...Levey-Jennings (L-J) plots are used to monitor the long-term stability of the instrument using Boule blood controls." Instructions for printing the L-J charts were included in the section. 3. During an interview on 03/23/2021 at 3:15 PM, the surveyor asked TP #1 if the laboratory printed the Hematology QC L-J charts. TP #1 stated she had printed some the L-J charts after the previous survey (June 2018 and January 2019), however she had stopped printing them. TP #1 confirmed the laboratory had no other method to monitor the QC for shifts and trends.